### **Environmental Protection Agency**

### § 716.40 EPA requests for submission of further information.

EPA may, by letter, request a person to submit or make available for review the following information after the initial reporting under §§ 716.30 and 716.35. If the requested submissions are not made, EPA may subpoena them under section 11 of TSCA, 15 U.S.C. 2610.

- (a) Submission of underlying data of the kind described in 716.10(a)(4) by persons who submit copies of studies under 716.30 or list studies under 716.35(a)(1) or 716.35(a)(2).
- (b) Submission of preliminary reports of ongoing studies by persons who list the studies under  $\S716.35(a)(1)$  or  $\S716.35(a)(2)$ .
- (c) Submission of copies of studies by persons listed under §716.35(a)(3) as possessing them.

## § 716.45 How to report on substances and mixtures.

Section 716.120 lists substances and mixtures, in order by Chemical Abstract Service Registry Number and by alphabetical order. Studies of listed substances and listed mixtures shall be reported as follows:

- (a) When a substance is individually listed under §716.120(a), studies of the substance and studies of mixtures known to contain the substance must be reported as studies of that substance.
- (b) When two or more substances are listed as a mixture under §716.120(b), studies of the listed mixture and studies of any mixture known to contain the listed mixture must be reported as studies of the listed mixture.
- (c) Studies of the following preparations of a substance must be reported as studies of the substance itself, not as studies of mixtures known to contain the substance.
- (1) The substance in aqueous solution.
- (2) The substance containing a small amount of an additive, such as a stabilizer, emulsifier, or other chemical added for purposes of maintaining the integrity or physical form of the substance.

(3) The substance of the grade/purity specified in each rule promulgated under 15 U.S.C. 2607(d).

[51 FR 32726, Sept. 15, 1986, as amended at 63 FR 15774, Apr. 1, 1998]

# §716.50 Reporting physical and chemical properties.

Studies of physical and chemical properties must be reported under this subpart if performed for the purpose of determining the environmental or biological fate of a substance, and only if they investigated one or more of the following properties:

- (a) Water solubility.
- (b) Adsorption/desorption on particulate surfaces, e.g., soil.
  - (c) Vapor pressure.
- (d) Octanol/water partition coefficient.
- (e) Density/relative density (specific gravity).
- (f) Particle size distribution for insoluble solids.
  - (g) Dissociation constant.
- (h) Degradation by photochemical mechanisms—aquatic and atmospheric.
- (i) Degradation by chemical mechanisms—hydrolytic, reductive, and oxidative.
- (j) Degradation by biological mechanisms—aerobic and anaerobic.

#### § 716.55 Confidentiality claims.

- (a)(1) Section 14(b) of TSCA provides that EPA may not withhold from disclosure, on the grounds that they are confidential business information. health and safety studies of any substance or mixture that has been offered for commercial distribution (including for test marketing purposes and for use in research and development), any substance or mixture for which testing is required under TSCA section 4. or any substance for which notice is required under TSCA section 5, except to the extent that disclosure of data from such studies would reveal-
- (i) Processes used in the manufacturing, importing, or processing of the substance or mixture, or
- (ii) The portion of a mixture comprised by any of the substances in the mixture.
- (2) Any respondent who wishes to assert a claim that part of a study should be withheld from disclosure because